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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,947	03/10/2004	Salomon Amar	50047/019002	4604

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EXAMINER	
JOIKE, MICHELE K	
ART UNIT	**PAPER NUMBER**
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,947	AMAR ET AL.	
	Examiner	Art Unit	
	Michele K. Joike, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 27-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on May 30, 2006 is acknowledged. The traversal is on the ground(s) that Group III should be rejoined since there is no undue search burden because both groups recite a LITAF polypeptide fragment that includes amino acids of SEQ ID NO: 1. This is not found persuasive because Group II is directed to a product containing the LITAF domain, while Group II is drawn to a method of identifying inhibition of LITAF binding. The product could be used in other methods, for example, production of an antibody. A search for an inhibitor of a binding domain would not correspond with a search for a specific sequence because different databases are used, and hence the search would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18 and 27-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 30, 2006. Claims 19-26 are examined.

Specification

The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through

1.825 because sequences were set forth that lack sequence identifiers. These sequences include the sequences listed in the claims, throughout the specification, including the abstract, and drawings. Examples include, but are not limited to, pages 4, 5, 6, 20, 26-30, 35, 37 of the specification and Figure 3. Nucleotide sequences with 10 or more nucleotides and amino acid sequences with 4 or more amino acids require sequence identifiers.

Appropriate correction is required.

Claim Objections

Claims 21-23 are objected to because of the following informalities: Claims 21-23 are missing sequence identifiers. Additionally, in line 4 of claim 23, "effect" should be "affect". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites a "peptide fragment of a peptide having SEQ ID NO: 1". It is unclear if the fragment is SEQ ID NO: 1, or if the fragment is part of the peptide comprising SEQ ID NO: 1. The claim does not distinctly point out the metes and bounds of "fragment".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Since the peptides can occur in nature, as recited in the specification, they read on products of nature. It is suggested that Applicant claim the peptides as isolated peptides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,077,693.

Applicant teaches a peptide fragment comprising SEQ ID NO: 1 which enhances TNF-α transcription by interacting with a TNF-α promoter nucleotide sequence, and a peptide fragment comprising SQTWREPGAAGSPFHL.

US 6,077,693 teaches SEQ ID NO: 1. If the peptide fragment is SEQ ID NO: 1, then SEQ ID NO: 1 from US 6,077,693 teaches the peptide fragment. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition

patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id.* MPEP 2111.04. Therefore, since SEQ ID NO: 1 is a known human promonocyte associated protein, the discovery that PRMNC can enhance transcription of TNF-α does not render SEQ ID NO: 1 patentably new, and is an inherent property. The sequence SQTWREPGAAGSPFHL is amino acids 165-180 of SEQ ID NO: 1. Therefore, SQTWREPGAAGSPFHL of SEQ ID NO: 1 US 6,077,693 satisfies the limitations of claim 21 which is a peptide fragment comprising SQTWREPGAAGSPFHL, and claim 19, if the peptide fragment is a portion of SEQ ID NO: 1.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by WO02086094.

Applicant teaches the peptide fragment comprising a naturally occurring allelic variant of SQTWREPGAAGSPFHL.

WO02086094 teaches sequence PQTWLEKGMAAGSPF, which is amino acids 449-463 of SEQ ID NO: 18. SEQ ID NO: 18 is the deduced amino acid sequence of *crtI* gene encoded by ORF 9. Absent evidence to the contrary and any definition in the present disclosure, PQTWLEKGMAAGSPF is a naturally occurring allelic variant. There are only two amino acid substitutions, one conserved (R to L), and one amino acid addition. *crtI* is a naturally occurring gene, thus PQTWLEKGMAAGSPF is a naturally occurring allelic variant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,566,501. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 recites "[a]n isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 1, wherein the polypeptide is a transcription factor involved in regulating lipopolysaccharide (LPS) induced Tumor Necrosis Factor-alpha (TNF-.alpha.) gene expression, and claim 19 of the instant application is drawn to a peptide fragment of a peptide having SEQ ID NO: 1, whereby said fragment enhances TNF-α transcription by interacting with a TNF-α promoter nucleotide sequence. If the claim is interpreted to read that the peptide fragment is SEQ ID NO: 1, as discussed above in the 112(2) rejection section, then the claims are drawn to the same invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER